

<b>Case Number:</b>	CM14-0029089		
<b>Date Assigned:</b>	03/19/2014	<b>Date of Injury:</b>	04/07/2013
<b>Decision Date:</b>	04/15/2014	<b>UR Denial Date:</b>	02/10/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/05/2014

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The expert reviewer is Board Certified in Physical Medicine and Rehabilitation, has a subspecialty in Pain Medicine and is licensed to practice in California. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker had an original date of injury on April 7, 2013. The patient has chronic low back pain and has diagnoses of lumbar disc displacement, lateral recess stenosis, left leg radiculopathy, and lumbar disc degeneration. The disputed issue is a request for H wave unit purchase. According to the utilization review, the submitted medical documentation includes an H-Wave outcome report on date of service November 12, 2013 that indicates that the injured worker utilized the H wave unit for low back pain with a 40% improvement in back pain. The claimant also notes the ability to sit longer, sleep better, and stand longer. Other documented treatments prior to H-Wave stimulation include use of a TENS unit, physical therapy, and medication. A utilization review on date of service February 10, 2014 noncertified the request for H wave stimulator purchase. The rationale was that the claimant is "still temporarily totally disabled based upon the December 17, 2013 report and there is no indication that the device requested will be used in an adjunct with a skilled intervention." The reviewer argued that "without any significant change in the claimant's work status, medical necessity is not evident."

### IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

**H WAVE UNIT AND SUPPLIES (PURCHASE AFTER THE 30 DAY TRIAL):** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines H Wave Stimulation Page(s): 117-118.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation H Wave Stimulation.

**Decision rationale:** The CA MTUS specifies on page 117-118 of the Chronic Pain Medical Treatment Guidelines the following regarding H-wave stimulation (HWT): "Not recommended as an isolated intervention, but a one-month home-based trial of H-Wave stimulation may be considered as a noninvasive conservative option for diabetic neuropathic pain (Julka, 1998) (Kumar, 1997) (Kumar, 1998), or chronic soft tissue inflammation if used as an adjunct to a program of evidence-based functional restoration, and only following failure of initially recommended conservative care, including recommended physical therapy (i.e., exercise) and medications, plus transcutaneous electrical nerve stimulation (TENS). In a recent retrospective study suggesting effectiveness of the H-wave device, the patient selection criteria included a physician-documented diagnosis of chronic soft-tissue injury or neuropathic pain in an upper or lower extremity or the spine that was unresponsive to conventional therapy, including physical therapy, medications, and TENS. (Blum, 2006) (Blum2, 2006) There is no evidence that H-Wave is more effective as an initial treatment when compared to TENS for analgesic effects. A randomized controlled trial comparing analgesic effects of H-wave therapy and TENS on pain threshold found that there were no differences between the different modalities or HWT frequencies. (McDowell2, 1999) [Note: This may be a different device than the H-Wave approved for use in the US.] Regarding tissue repair, another study suggests that low-frequency HWT may produce direct localized effects on cutaneous blood flow, a finding relevant for clinicians working in the field of tissue repair. (McDowell, 1999) The one-month HWT trial may be appropriate to permit the physician and provider licensed to provide physical therapy to study the effects and benefits, and it should be documented (as an adjunct to ongoing treatment modalities within a functional restoration approach) as to how often the unit was used, as well as outcomes in terms of pain relief and function. Rental would be preferred over purchase during this trial. Trial periods of more than one month should be justified by documentation submitted for review. While H-Wave and other similar type devices can be useful for pain management, they are most successfully used as a tool in combination with functional improvement. H-wave stimulation is a form of electrical stimulation that differs from other forms of electrical stimulation, such as transcutaneous electrical nerve stimulation (TENS), in terms of its waveform. While physiatrists, chiropractors, or podiatrists may perform H-wave stimulation, H-wave devices are also available for home use. H-wave stimulation is sometimes used for the treatment of pain related to a variety of etiologies, muscle sprains, temporomandibular joint dysfunctions or reflex sympathetic dystrophy. In fact, H-wave is used more often for muscle spasm and acute pain as opposed to neuropathy or radicular pain, since there is anecdotal evidence that H-Wave stimulation helps to relax the muscles, but there are no published studies to support this use, so it is not recommended at this time. H-wave stimulation has also been used to accelerate healing of wounds, such as diabetic ulcers. H-wave electrical stimulation must be distinguished from the H-waves that are a component of electromyography. (BlueCross BlueShield, 2007) (Aetna, 2005). Recent studies: A recent low quality meta-analysis concluded that the findings indicate a moderate to strong effect of the H-Wave device in providing pain relief, reducing the requirement for pain medication and increasing functionality, with the most robust effect observed for improved functionality, suggesting that the H-Wave device may facilitate a quicker return to work and other related daily activities. The low quality rating for this "meta-analysis" is primarily because the numbers were dominated by results from studies that were not prospective randomized controlled trials, but instead were retrospective observational studies using a patient survey, the H-Wave Customer Service Questionnaire, without a prospective control group. More definitive results may be on the way. According to this

study, "double-blinded studies of the H-Wave device are currently underway and results will be awaited with interest." (Blum, 2008)" In the case of this injured worker, there is documentation of a previous home TENS trial. The patient had a three-week trial duration in which tends was felt to not provide adequate relief, and the date of the trial was October 22, 2013. This was documented in a note on date of service November 12, 2013. In the follow-up note, there is no documentation of functional improvement. This is defined by guidelines as a change in work status or a clinically significant improvement in activities of daily living. Given the lack of documentation, this request for H wave stimulation purchase is recommended for noncertification.